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Unanswered Questions On FDA-USDA Cell Culture Agreement

By **Robert Hibbert and Amaru Sanchez** (April 5, 2019, 3:05 PM EDT)

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In a closely watched play between two federal powers, the U.S. Food and Drug Administration and the U.S. Department of Agriculture issued the text of a formal agreement last month detailing the division of responsibility between the two agencies over the emerging and much-discussed category of human food produced using cell culture technology, derived from cell lines of USDA-amenable species and required to bear a USDA mark of inspection.[1]

The document is consistent with the joint oversight approach discussed in the Nov. 16, 2018, statement by USDA secretary Sonny Perdue and FDA commissioner Scott Gottlieb.[2] However, it raises almost as many questions as it answers. Still, despite the uncertainty, it provides the clearest definitions we have on how the safety, suitability and marketing of such products is to be overseen by the two agencies.

In order to understand the agreement, it may be useful to separate pending issues into three separate areas: (1) premarket review (how such products are to be evaluated before being allowed to move into production for human food purposes); (2) ongoing oversight (supervision of actual food-processing operations); and (3) marketing (how the product is to be labeled and advertised in commerce).

Premarket Review

The FDA takes the lead in this area. The agreement specifies that the FDA will be responsible for conducting a premarket consultation process to evaluate production materials and processes in manufacturing controls, including the oversight of tissue collection, cell lines and banks, and all components and inputs.

Further, the FDA will oversee proliferation and differentiation of cells through the time of harvest. Within this area it reserves the right to conduct appropriate inspections and follow-up activities, initiate enforcement actions and provide addition regulation and guidance as appropriate.

Finally, at harvest, the FDA will be responsible for coordinating transfer of oversight to the USDA's Food Safety and Inspection Service, or FSIS, including providing information necessary for the USDA to determine whether such materials are eligible to be processed into meat or poultry products.

Ongoing Oversight

After the FSIS takes over, the USDA is responsible for integrating the production of these foods into the already established inspection system. This includes the requirement of continuous inspection, as overseen by the daily presence of a federal inspector, as well as the establishment and application of an effective hazard analysis critical control point, or HACCP, program.[3]

Products that successfully move through such systems are to be eligible for the same USDA mark of inspection that traditional meat and poultry products receive. There are a few exceptions: It will not apply to cell-cultured protein products or seafood products, which will remain under FDA jurisdiction (with limited exceptions). The FDA has its own HACCP requirement, which does not require or provide continuous inspection.[4]

Marketing

Finally, the FSIS commits itself in the document to develop, as needed, additional requirements to ensure the accurate labeling of the human food products derived from the cultured cells of livestock and poultry.

Takeaways

Premarket Issues

While the initial clarification of the FDA's premarket gatekeeper role is helpful, it brings up several additional questions:

- What is the specific nature of the premarket evaluation process?
- What will be the timeline for any such review?
- Will the FDA be issuing any sort of affirmative sanction of such products, as opposed to the absence of any objections?
- Will any type of acceptance, either through an active or passive process, be attached to a particular production facility, a particular class of product or some other distinction?
- Will new regulations need to be promulgated before any of this takes place?

Before this joint agreement, the FDA has pointed to existing procedures such as the Generally Recognized as Safe notification program, food contact notification procedures and new technology guidelines as points of reference, while also suggesting that a new process, focusing upon variables unique to this industry, needs to be crafted.[5]

The answers to the above questions will dictate what information the industry will need to gather and submit to the FDA to provide an assurance that foods produced using animal cell culture technology are safe and not adulterated.

Oversight Issues

FSIS inspection will apply to all forms of food processing for what is deemed to be meat and poultry once the transfer of eligible cell material has happened. While the processing will be subject to continuous inspection and mandatory HACCP, there are underlying complications and nuances.

For example, the FDA's statement of responsibilities includes providing the FSIS with information necessary to determine whether harvested materials are eligible to be processed into the meat and poultry products. This suggests the need for some affirmative endorsement of safety by the agency, which is something the FDA does not typically do.

Also, all meat and poultry items for further processing subject to FSIS inspection must be derived from the carcasses of animals that have also been subject to both premortem and postmortem inspection by that same agency. This is a specific set of scientific and legal questions that apply to cell-cultured products, but that aren't answered under the new framework.

Labeling

The biggest debate in this area centers on questions about how these products are identified and labeled within the marketplace — more specifically, whether they can maintain access to the traditional terminology (i.e., "ground beef" or "sliced turkey") applied to such products.

At one extreme, some proponents of the new technology have asserted that the finished product itself will ultimately have characteristics identical to traditional items, and thus can be identically labeled. At the other extreme, it is argued that traditional meat and poultry items are apples, and cell-cultured products are oranges, and they need to be emphatically differentiated as such.

While this agreement addresses some of the questions on how federal agencies are handling this type of product, there are still questions about what policies and requirements will be issued at the state level. As has been widely reported, there has been a spate of recent legislative activity centered in states with significant local livestock industries, advancing the view that such traditional terminology should only be applicable to products derived from the carcasses of live animals.

State activity is expected to continue despite the clear federal preemption that attaches to the labeling of any meat and poultry products under FSIS jurisdiction.[6] Once again, seafood products are a bit of a wildcard in this area, since they do not enjoy the benefits of such clear statutory protection.

Conclusion

The joint agreement commits both agencies to a cooperative approach to these issues, drawing upon their respective areas of expertise and jurisdiction. However, a host of additional details must be resolved prior to the marketing of this much-discussed new category of food products.

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[1] FDA Statement, USDA and FDA Announce a Formal Agreement to Regulate Cell-Cultured Food Products from Cell Lines of Livestock and Poultry (Mar. 7, 2019), https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm632916.htm?utm_campaign=030719_PR_Formal%20Agreement%20to%20Regulate%20Cell-Cultured%20Food%20Products&utm_medium=email&utm_source=Eloqua.

[2] FDA Statement, Statement from USDA Secretary Perdue and FDA Commissioner Gottlieb on the regulation of cell-cultured food products from cell lines of livestock and poultry (Nov. 15, 2018), https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm626117.htm.

[3] 21 U.S.C. §§ 455, 602-606.

[4] See 21 CFR Part 123; see also FDA, Seafood HACCP (page last updated Jan. 29, 2018), https://www.fda.gov/food/guidanceregulation/haccp/ucm2006764.htm.

[5] FDA, Presentation by FDA: FDA's Historical Experience with Food Safety Evaluation and Future Considerations (July 12, 2018), https://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/ucm610138.htm.

[6] See Law360, State Meat Label Restrictions Face Preemption Challenges (Mar. 6, 2019), https://www.law360.com/articles/1135648/state-meat-label-restrictions-face-preemption-challenges.